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Date June 10, 2004 **Pages including cover** 25

Subject Response to Notice of Non-compliant Amendment

Re: Application of Gregor John McLennan ANDERSON et al.
U.S. Serial No.: 10/089,760; Filed: April 2, 2002
Title: *Medicament Delivery System*
Attorney Docket No. PG3786USw

Attached:

1. Transmittal Form (with a Certificate of Transmission (37 CFR 1.8(a))
2. Response to Notice of Non-compliant Amendment (23 pages)

PTO/SB/21 (08-03)
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/089,760
Filing Date	April 2, 2002
First Named Inventor	Gregor John McLennan ANDERSON
Art Unit	2632
Examiner Name	Mullen, Thomas J.
Total Number of Pages in This Submission	
Attorney Docket Number	PU37B6USw

ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☒ Amendment / Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
- ☐ After Allowance communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) *(please identify below)*:

Remarks

Applicants believe that no fee is required for this submission. However, the Commissioner is hereby authorized to charge any fees required or credit any overpayment to Deposit Account No. 07-1392.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	**Robert J. Smith** **Registration No. 40,820** **Telephone: (919)483-9616**
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Date	**June 10, 2004**

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria,VA 22313-1450 on the

Typed or printed name	**Marjorie J. Pfeiffer**		
Signature	Marjorie J. Pfeiffer	Date	**June 10, 2004**

#11 C 6-21-04

IN THE UNITED STATES PATENT OFFICE

Applicant	:	ANDERSON, Gregor, et al.
Application No.	:	10/089,760
Filed	:	4/2/2002
Title	:	Medicament Delivery System
Grp./A.U.	:	2632
Examiner	:	Mullen, Thomas
Docket No.	:	PG3786USW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NOTICE OF NON-COMPLIANT AMENDMENT

Applicants submitted an Amendment B on 4/9/2004 in reply to the Office Action dated 10/7/2003. On 5/21/2004, the Patent Office issued a Notice of Non-Compliant Amendment ("the Notice") concerning Amendment B. The following is a response to the Notice.

In the Notice, the Legal Instruments Examiner indicated that Amendment B was non-compliant as the "instructions don't coincide with the Specification." The Notice failed to identify where the instructions didn't coincide, so applicants have made a point-by-point review of Amendment B to determine what difficulties the Legal Instruments Examiner may have encountered.

The present Application was filed based on PCT application PCT/EP00/09291 that published as WO/24690. Applicant's file copy of the application appears to mirror the WO/24690 publication. Upon entry into the US National Phase with this application, applicants filed a "Preliminary Amendment A", which added, as a 1st paragraph on Page 1 of the specification, after the Title, the lineage and priority of the application. This became the new first full paragraph of the specification on page 1 referred to in Amendment B.

The instructions provided in Amendment B included the new first paragraph as the first full paragraph on Page 1. Its possible that the Legal Instrument Examiner did not take the Preliminary Amendment into account before tending the Notice.

Applicants note in this present review, that a typographical error is present in the instructions on page 9 of Amendment B, concerning an amendment to page 15 of the Specification. This instruction should have been "On page 15, please amend the paragraph beginning on ~~page~~ line 32 as follows:" Further, an additional typographical error occurred on Page 11, of Amendment B, concerning page 17. This instruction should have been "On page 17, amend the paragraph beginning on line ~~33~~13, as follows:" In both cases, the full text of the paragraphs were provided, making the typographical errors very identifiable and correctable.

Applicant assumes that the instructions as to the amendments to the claims were clear, and therefore, no further discussion will be made of the claim amendments in this Response.

Below is a clean text version of all the pages of the specification (red-lining has been removed). This clean version starts with the text of the application, as reflected in the Published PCT version, and includes the amendments made in Preliminary Amendment A and Amendment B (correcting the instructions for the amendments on pages 15 and 17 of the specification which were made in Amendment B).

Application No. 10/089,760
Attorney Docket No. PG3786USW

CLEAN TEXT /CURRENT STANDING OF PAGE 1:

Medicament delivery system

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is filed pursuant to 35 USC 371 as a United States National Phase Application of Serial No. PCT/EP00/09291 filed 22 Sept. 2000, which claims priority from GB 9923272.8 filed 1 October 1999; GB 0011029 filed 9 May 2000; and GB 00205419.9 filed 22 August 2000, each in the United Kingdom.

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to a system for the delivery of medicament having an electronic data management system. The system is capable of wireless communication with an entrypoint to a network computer system to enable communication of data between the network computer system and the electronic data management system.

DESCRIPTION OF THE RELATED ART

It is common prescribing practice for a doctor to prescribe a patient with medicament in a medicament dispenser together with instructions for patient administration of the medicament according to a defined treatment regimen. The patient typically therefore, receives instructions relating to the correct use of the dispenser together with recommended dosing amounts, dose intervals and treatment period. The patient is then trusted to follow the treatment regimen as set by the doctor.

A limitation associated with this practice is that the treatment regimen is set at the time of prescription and can therefore not account for changes in the patient's condition over the treatment period. A further limitation associated with this practice is that the onus is on the patient to comply with the doctor's instructions. Occasionally, patients will forget to

take the medicament or will vary the treatment regimen in an unpredictable manner with possible consequences for the success of the treatment.

A variation on the above-described prescribing practice involves the use by a patient of a diagnostic device which enables data relating to their medical condition to be gathered on a regular basis. This data may for example, be collected prior to administration of any medicament and a correct dose amount calculated on the basis of the diagnostic data. An example of this practice would be that of a diabetic who checks their blood-sugar levels in order to calculate a required dose of insulin.

In developments of the practice variation, the diagnostic device may be integrated with the delivery system. Information relating to the patient's condition

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and usage of the dispenser may thus be displayed to the patient to enable the better management of their medical condition. The information may further be stored in a memory such that it may be recalled at a later time to enable historic analysis of the progress of the condition and effect of the treatment. Dispensers employing electronic data management systems have been proposed for this purpose.

US-A-5,363,842 describes an inhalation device for use in delivering inhalable medicament. The device enables data relating to the patient's breathing pattern to be collected, analysed and displayed to the patient. The data is stored in a memory for download to a workstation at the clinic.

WO99/35588 describes a method for managing the administration of medicine and in particular, monitoring patient compliance with a prescribed treatment regimen. The method relies on input of patient data to a central computer workstation. The central computer workstation calculates and transmits dosage data to a dispensing device via a communications link. The dispensing device delivers drug in accord with the dosage data.

BRIEF SUMMARY ON THE INVENTION

The Applicants have now developed an improved system for the delivery of medicament which employs an electronic data management system. The system is capable of wireless communication with a network computer system to enable communication of data between the network computer system and the electronic data management system. The system therefore, provides the advantage of enabling data transfer with a network of computers, which network can be made accessible to diverse remote information sources, which may in turn be networked together for cross-transfer of data. The patient therefore, has ready access to diverse, possibly inter-connected, remote information sources capable of providing disease management information. In turn, the system can feed information, such as compliance information, back to any remote information source having access to the network computer system. The system can also be integrated with a healthcare

management system for remote prescribing or remote variation or control of the prescribing regime. The healthcare management system will typically be under the control of a healthcare professional such as a doctor.

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According to further aspects of the present invention there are provided methods for use of the system herein and software for the implementation thereof.

Embodiments of systems according to the invention will now be described with reference to the accompanying drawings in which:

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE INVENTION

Figure 1 is a schematic representation of a first system in accord with the present invention;

Figure 2 is a schematic representation of a second system in accord with the present invention;

Figures 3 and 4 are schematic representations of third and fourth systems in accord with the present invention in which the elcctronic data management system integrates with a system for electronic prescription of medicament;

Figure 5 is a system diagram of a further system in accord with the present invention;

Figure 6 is a system diagram of a central controller unit for use in accord with the present invention; and

Figure 7 is a system diagram of a patient electronic data manager for use in accord with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1 shows a standard-form metered dose inhaler for the delivery of inhalable medicament comprising a tubular housing 10 in which an aerosol container 12 is located.

The housing is open at one end (which will hereinafter be considered to be the top of the device for convenience of description) and is closed at the other. A dispensing outlet 14 leads laterally from the closed end of the housing 10. In the embodiment illustrated, the outlet 14 is in the form of a mouthpiece intended for insertion into the mouth of the patient but it may, if desired, be designed as a nozzle for insertion into the patient's nostril.

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In an alternative form, as alternatively depicted in Figure 2, the system is suitable for the delivery of inhalable medicament and additionally comprises a sensor 132, which senses the breath of a user, wherein the sensor communicates breath data to the electronic data management system. In one aspect, the sensor comprises a breath-movable element which is movable in response to the breath of a patient. More preferably, the breath-movable element is selected from the group consisting of a vane, a sail, a piston and an impeller. In another aspect, the sensor comprises a pressure sensor for sensing the pressure profile associated with the breath of a user. In a further aspect, the sensor comprises an airflow sensor for sensing the airflow profile associated with the breath of a user. In a further aspect, the sensor comprises a temperature sensor for sensing the temperature profile associated with the breath of a user. The temperature of the inhaled and exhaled part of the breath cycle varies and may, thus, be used as a measurement tool. In a further aspect, the sensor comprises a moisture sensor for sensing the moisture profile associated with the breath of a user. The moisture content of the inhaled and exhaled part of the breath cycle varies and this also may be used as a measurement tool. In a further aspect, the sensor comprises a gas sensor for sensing the oxygen or carbon dioxide profile associated with the breath of a user. The chemical profile of the inhaled and exhaled part of the breath cycle varies and this further may be used as a measurement tool. Suitably, the breath data includes breath cycle data or peak flow data.

Suitably, the system additionally comprises an actuator 133 for actuating the dispensing mechanism, said actuator being actuable in response to a trigger signal from the transmitter. The actuator triggers a mechanism leading to the release of medicament from aerosol valve 134.

The aerosol container 12 is located in the housing 10 so that one end protrudes from the open top of the housing 10. The aerosol container 12 has an outlet valve stem (see for example, 131 in figure 2) at one end which connects with a support (not shown) in the housing 10. To dispense the dose, the protruding portion of the aerosol container 12 is

depressed to move the container 12 relative to the valve stem to open the valve and dispense medicament into the outlet 14 from which it can be inhaled by a patient.

The dispenser includes an electronic data management system 13 in the form of an integrated circuit preferably integrated into one or more integrated circuit chips and comprised within the housing. The electronic data management system 13 comprises a memory 16 for storage of data; a microprocessor 17 for performing operations on said data; and a transmitter 18 for transmitting a signal relating to the data or the outcome of an operation on the data. The user may access the electronic data management system by use of push-buttons 20 and toggle menu-button 24. Display 30 allows for display of menu choices and data from the electronic data management system. The dispenser communicates via communications transceiver (also referred to as "communicator") 40 to network computer system 50, through a gateway 52. The network computer system 50 comprises a secure extranet computer system. Remote information sources 60, 62, 63, 64, 66, 68 also have access to the extranet. In more detail, the remote information sources comprise a medicament prescriber 60, a pharmacy 62, a weather monitoring station 64, a pollution monitoring station 66 and a medicament manufacturer 68. Other remote information source(s) 63 include, but are not limited to an emergency assistance provider and a research establishment. Two-way data transfer is possible between the electronic data management system and the network computer system 50 via the communications transceiver 40. Information transfer is thus possible between the electronic data management system and any of the remote information sources 60, 62, 63, 64, 66, 68. Information received from any of the remote information sources 60, 62, 63 64, 66, 68 may be utilised by the electronic data management system to vary the recommended medicament dose for delivery to the patient.

Figure 2 shows a variation of the system of Figure 1. The system comprises standard-form metered dose inhaler for the delivery of inhalable medicament comprising tubular housing 110, an aerosol container 112, a valve stem 131, an aerosol valve 134, and dispensing outlet 114. Operation of the inhaler is as described above with reference to Figure 1.

The dispenser includes an electronic data management and communications system 140 comprised within the housing 110. Display 130 allows for limited

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display data from the electronic data management system. The dispenser readily communicates via chip 140 to palmtop computer 170. The communication is via spread spectrum radiofrequency signals operable over a relatively short range (e.g. up to ten metres). The palmtop computer 170 has a more sophisticated display 172 including a graphical user interface comprising menu-entry screens from which selections may be made using toggle menu-button 174.

The user accesses the electronic data management system of the dispenser 110 through the palmtop computer 170. The electronic data management system interacts with the palmtop computer via communicator 140. The palmtop computer 170 itself can communicate through a telecommunications link with network computer system 150, through a gateway 152. The network computer system 150 comprises a secure extranet computer system. As in Figure 1, remote information sources may also have access to the extranet. Two-way data transfer is possible between the electronic data management system and the network computer system 150 via the communications links with the palmtop computer 170. Information transfer is thus possible between the electronic data management system 140, palmtop computer 170 and any of the remote information sources. The system may additionally comprise a geographic positioning system, depicted as optional component 141 (also depicted as 41 in Fig. 1), such as a global positioning system or a system which relies on the use of multiple communications signals and a triangulation algorithm.

Figure 3 shows a system herein in which patient electronic data management system in dispenser 210 communicates wirelessly with geographically distant network computer system 250. The network computer system 250 is itself accessible (i.e., wirelessly or via a modem link) by the system of a medicament prescriber 260 (e.g. a doctor's surgery system) and by the system of a pharmacist 262.

The system of Figure 3 may be employed in the remote assessment of a patient and electronic prescribing therefor as follows. The patient data management system in dispenser 210 communicates data relating to the medical condition of the patient to the network computer system 250. The medicament prescriber 260 accesses this data e.g. ~~by~~ wirelessly by use of a palmtop communications and data management device and makes a judgement as to prescription needs. If a new prescription is needed the prescriber sends a 'prescription authorisation' signal to the network computer system 250. The pharmacist 262 then accesses the network computer system to receive the 'prescription authorisation' signal which authorises them to make up the prescription for the patient.

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The system of Figure 4 is a variation of the system of Figure 3 in which patient electronic data management system in dispenser 310 communicates wirelessly with geographically distant network computer system 350. The network computer system 350 is itself accessible by the system of a medicament prescriber 360 (e.g. via a modem-enabled personal computer of a doctor). The prescriber system 360 may also access second network computer system 354 which is accessible by the system of a pharmacist 362. In an alternative herein, the second computer system 354 may be integral with the system of the pharmacist 362 or be a dedicated secure prescription system accessible only to the prescriber and the pharmacist.

The system of Figure 4 is employed in the remote assessment of a patient and electronic prescribing therefor as follows. The patient data management system in dispenser 310 communicates data relating to the medical condition of the patient to the network computer system 350. The medicament prescriber 360 wirelessly accesses this data and makes a judgement as to prescription needs. If a new prescription is needed the prescriber sends a 'prescription authorisation' signal to the second network computer system 354. The pharmacist 362 then accesses the network computer system to receive the 'prescription authorisation' signal which authorises the pharmacist to make up the prescription for the patient.

Figure 5 shows a representative system herein comprising an electronic patient data management system in dispenser 410 which would be under the control of the patient. Associated with the patient electronic data management system in dispenser 410 there is a patient communicator 442 which is capable of wireless communication with a network computer system 450. The system also comprises an authorised user interface 480 having associated authorised user communicator 482 which is capable of communicating with the network computer system 450. Central controller unit 490 is in two-way communication with the network computer system 450.

The system of Figure 5 is shown in patient 'data upload mode' wherein patient data 444 is wirelessly communicated from the patient data management system to the

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communicator 442 and patient data management system. The system is also shown in authorised user 'enquiry mode' in which a database enquiry 484 is communicated to the network computer system 450 and a response received 486 via the authorised user communicator 482 to the authorised user interface 480.

Figure 6 shows the structure of the central controller 590 in more detail. The central controller includes a data storage device 591, central processor (CPU) 592, cryptographic processor 593, RAM 594, ROM 595, payment processor 596, operating system 597 and billing processor 598.

The components of the central controller 590 must be selected to be capable of handling sufficiently large volumes of data. The data storage devices, processors and operating system and other components may be selected from those commercially available.

The data storage device 591 is partitioned to include plural databases. The databases comprise a patient data database 548 which comprises data communicated from the patient electronic data manager; a patient database 549 which includes patient details such as name, address and possibly medical history; an authorised user database 589 which includes details of authorised users of the system; a billing database 561 for use in billing authorised users on retrieval of data; a payment database 563 for use in payment of other authorised users in return for data provided; and a crypto key database 565 comprising encryption information.

It will be appreciated that various parts of the system are designed to co-operate with each other in use. For example, the cryptographic processor 593 will access the crypto key database 565 to enable performance of user authentication. Together these crypto elements may form a secure access gateway to the patient data database.

Figure 7 shows a patient electronic data manager 613 comprised with a respiratory drug delivery system. The electronic data manager 613 comprises a central processor unit (CPU) 621; RAM 622; ROM 623 and a

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cryptographic processor 624. The CPU 621 receives patient data from sensor 615 which may for example be a breath sensor or a sensor detecting actuation of the respiratory drug delivery system. The received data is storable in data storage device 625 which includes two databases, one for storage of patient medical data 626 and one for storage of personal patient data 628. The CPU 621 is associated with man machine interface 620 for receipt of patient input commands and display driver 632 and display 630 for display of information to the patient. The CPU 621 is further associated with communications port 640 which links via wireless communications link 642 to the central controller 690 of a network computer system (not shown).

It will be appreciated that the basic structure of the patient data management system 613 of Figure 7 can act as an authorised data communicator for making enquiry requests to the databases on the network computer system and receiving responses therefrom. It will also be appreciated that the structure of the patient data management system could be adapted by removal of the sensor 615 to form a non-patient authorised data communicator which would not be comprised within a respiratory drug delivery system.

The system of the invention is in one aspect suitable for dispensing medicament for the treatment of respiratory disorders such as disorders of the lungs and bronchial tracts including asthma and chronic obstructive pulmonary disorder (COPD).

Appropriate medicaments may thus be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate (e.g., as the sodium salt), ketotifen or nedocromil (e.g., as the sodium salt); antiinfectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti- inflammatories, e.g., beclomethasone (e.g., as the dipropionate ester), fluticasone (e.g., as the propionate ester), flunisolide, budesonide, rofleponide, mometasone e.g., as the furoate ester), ciclesonide, triamcinolone (e.g., as the acetonide)

or 6α, 9α-difluoro-11β-hydroxy-16α-methyl-3-oxo-17α-propionyloxy-androsta-1,4-diene-17β-carbothioic acid S-(2-oxo-tetrahydro-furan-3-yl) ester; antitussives, e.g., noscapine;

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bronchodilators, e.g., albuterol (e.g., as free base or sulphate), salmeterol (e.g., as xinafoate), ephedrine, adrenaline, fenoterol (e.g., as hydrobromide), formoterol (e.g., as fumarate), isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol (e.g., as acetate), reproterol (e.g., as hydrochloride), rimiterol, terbutaline (e.g., as sulphate), isoetharine, tulobuterol or 4-hydroxy-7-[2-[[2-[[3-(2-phenylethoxy)propyl]sulfonyl]ethyl]amino]ethyl-2(3H)-benzothiazolone; adenosine 2a agonists, e.g., 2R,3R,4S,5R)-2-[6-Amino-2-(1S-hydroxymethyl-2-phenyl-ethylamino)-purin-9-yl]-5-(2-ethyl-2H-tetrazol-5-yl)-tetrahydro-furan-3,4-diol (e.g., as maleate); α_4 integrin inhibitors e.g., (2S)-3-[4-({[4-(aminocarbonyl)-1-piperidinyl]carbonyl}oxy)phenyl]-2-[((2S)-4-methyl-2-{[2-(2-methylphenoxy) acetyl]amino}pentanoyl)amino] propanoic acid (e.g., as free acid or potassium salt), diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium (e.g., as bromide), tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon; vaccines, diagnostics, and gene therapies. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament.

Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) or formoterol (e.g., as the fumarate salt) in combination with an anti-inflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate) or budesonide. A

particularly preferred combination is a combination of fluticasone propionate and salmeterol, or a salt thereof (particularly the xinafoate salt). A further combination of particular interest is budesonide and formoterol (e.g. as the fumarate salt).

Conclusion

Applicant's have made a good faith attempt to address any possible issue the Legal Instruments Examiner may have had in issuing the Notice. Without specific details about where the Examiner was having difficulty, it is impossible to make a more pointed response. Other than the typographical errors in the concerning amendment of pages 15 and 17, the possible overlooking of the amendments made in Preliminary Amendment A to the first page of the specification, and the remote possibility that PTO's copy of the specification and the applicant's file copy are not identical, applicant cannot identify any reason to support the Legal Instrument Examiner's finding of Non-Compliance.

Hopefully this Response will clarify any difficulties the office may be experiencing with this application.

In light of amendments made in the Preliminary Amendment and Amendment B (as clarified by this Response), applicants asserts that all issued raised by the Legal Instrument Examiner and the examiner in any outstanding office actions to date have been addressed. As such, the claims are asserted to be in condition for allowance. Applicant requests that a timely Notice of Allowance be issued in this case. If any matters exist that preclude issuance of a Notice of Allowance, the examiner is requested to contact the applicant's representative at the number indicated below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any fees required under 37 CFR Sections 1.16 and/or 1.17, and any necessary extension of time fees, to deposit Account No. 07-1392.

Application No.: 10/089,760
Attorney Docket No. PG3786USW

Respectfully submitted,

Dated: June 9, 2004

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